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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,994	01/19/2005	Robert J. Levy	RCHP-132US	1713
23122	7590	07/02/2007		
RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980			EXAMINER GILLESPIE, BENJAMIN	
			ART UNIT 1711	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,994	<b>Applicant(s)</b> LEVY ET AL.	
	<b>Examiner</b> Benjamin J. Gillespie	<b>Art Unit</b> 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 31-40 is/are rejected.
- 7) ☒ Claim(s) 24-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/17/2006, 2/21/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 16 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language “less prone” and “a polyurethane” render claim 16 indefinite because “less prone” is relative language and no explanation is given as to what limitations constitute “a polyurethane”. Similarly, the language “substantial” renders claim 31 indefinite because it is relative language.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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3. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

4. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10, 17-23, 31-32, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-20, 27-29 of copending Application No. 11/233,149. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim steroid lipid and cholesterol pendant modified polyurethanes and a process for their production.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, and 11-19, 31, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al ('011). Levy et al teach modified polyurethane and method for

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production comprising a lipid substituent pendant group from at least one urethane nitrogen and/or carbon atom, wherein the pendant is present in at least 10 micromoles for every gram of polyurethane, resulting in about 0.5 to 40% of the urethane nitrogens in the backbone of the polyurethane having a lipid substituent pendant (Abstract; col 4 lines 20-25). Furthermore, patentees teach that the modified polyurethane has different lipid substituents pendant from the urethane nitrogens and the resulting polymer exhibits improved chemical degradation resistance (Col 3 lines 35-60; col 7 lines 1-7).

7. Regarding the method of production, Levy et al explain that the polyurethane is reacted with a multifunctional linker reagent consisting of dibromoalkyl and/or bromo-epoxyalkyl compounds, followed by reacting the resulting bromo-modified polyurethane with the lipid substituent (Col 8 lines 37-52; col 9 lines 1-16; col 10 lines 45-67; col 11 lines 1-7). Finally, Levy et al teach the modified polyurethane may be used in cardiovascular implants, angioplasty devices, and cardiac catheters (Col 14 lines 41-42).

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al ('136). Thomas et al teach modified polyurethane having cholesterol pendant from at least one carbon atom (Col 2 lines 23-30; 45-52).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2-3 5-9, 20, 21, 23, 32-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al ('011) in view of Leong et al (2002/0045263). Aforementioned, Levy et al teach a phosphonate lipid-modified polyurethane useful in medicine for cardiovascular implants, angioplasty devices, and cardiac catheters, but there is no discussion as to what type of cell the implant is exposed to, specifically endothelial cells or a cholesterol modified lipid substituent. Although there is no specific teaching that the implant of Levy et al is directed towards endothelial cells, it would have been obvious to use the composition in such applications based on the motivation that patentees direct the invention towards cardiovascular, specifically angioplasty devices, which contact blood vessels.

10. Leong et al teach bioimplantable polymers having urethane and phosphate linkages, wherein the resulting polymer is useful in implants that provide anti-thrombogenic properties (Abstract, paragraphs 9, 56, and 304). In particular, Leong et al teach that when an implant that contains amphiphilic phosphates groups, it is advantageous for the polymer to also contain hydrophobic groups pendant from the polymer backbone, specifically steroid derivatives such as amino-functional cholesterol (Paragraphs 55, 120, and 121).

11. It would have been obvious to one of ordinary skill in the art at the time of invention to include pendant cholesterol groups in the polymer of Levy et al based on the motivation that when phosphonate groups are present in a bioimplant, it is preferred to additionally include said cholesterol groups, as taught by Leong et al.

12. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al ('011) in view of Smith ('423). As previously discussed, Levy et al renders obvious a lipid-modified polyurethane useful in anti-thrombogenesis medical devices that interact with

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endothelial cells, but there is no discussion of first seeding the implant with endothelial cells prior to implantation. Smith teaches vascular prosthesis having anti-thrombogenic characteristics, and in particular Smith teaches that it is beneficial to first seed endothelial cells on the implant prior to implantation because it provides the implant with improved adhesion when applied to the tissue surface (Col 1 lines 9-22).

13. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to utilize the teaching of Smith and attach endothelial cells to the bio-implant of Levy et al based on the motivation that it provides improved adhesion to living tissue in anti-thrombogenic applications.

***Allowable Subject Matter***

14. Claims 24-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

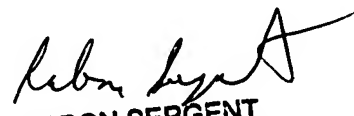
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Gillespie whose telephone number is 571-272-2472. The examiner can normally be reached on 8am-5:30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. Gillespie

  
RABON SERGENT  
PRIMARY EXAMINER